Government Response to the report of the Petitions Committee on the Petition of Catrina McGregor:

Inquire into Essure contraceptive device recall and compensate NZ women harmed

Presented to the House of Representatives

In accordance with Standing Order 256

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Introduction

1 The Government has carefully considered the Petitions Committee's report on the petition of Catrina McGregor: 'Inquire into Essure contraceptive device recall and compensate NZ women harmed.'

2 The Government welcomes the Committee's report and thanks the petitioner for bringing this sensitive and important issue to light. The Government acknowledges the suffering of women who have experienced harms from the Essure contraceptive device.

3 The Government responds to the report in accordance with Standing Order 256.

The petition and report of the Petitions Committee

4 The petition requested that the House of Representatives:

> initiate a full investigation into the promotion, funding, distribution and prescription of all Essure devices for NZ women; find, contact, and advise women who received these devices that they have been recalled; and offer full ACC coverage for any Essure-related care they may require.

5 The petitioner's reasoning for this request was:

> Essure devices are permanent contraceptive implants, recalled worldwide after women internationally suffered complications that I believe were catastrophic, life-threatening, and life-altering and included hysterectomies, agonising pain, bleeding, hair & tooth loss, and crippling immune system disorders, among other ill effects. While Essure has been recalled in NZ, women who received it have not been notified of the updated risks and ACC deny coverage for most Essure-related care.

6 The Government notes that the Petitions Committee:

6.1 recognises the suffering caused by the withdrawn Essure device,

6.2 accepts Medsafe's explanation of the process by which Essure was imported into, and then withdrawn from sale in New Zealand and, consequently,

6.3 does not think it appropriate to ask the House of Representatives to investigate Essure's distribution, nor to change ACC's processes to ensure the approval of all claims relating to Essure.

Petition Committee recommendations and Government response

7 The Committee's recommendations, by their nature, are long term and will require legislative reform. Work is currently underway to replace the Medicines Act 1981 with modern regulation of medicines and medical devices under a Medical Products Bill. It is the view of the Government that the Medical Products Bill will address the Committee's two substantive recommendations. Further details are set out in the response below.

8 **Recommendation 1**: That the Government amend the Medicines Act to require an application, assessment, and approval process for medical devices before they are supplied in New Zealand.

9 **Response:** The Government notes the recommendation to require an application, assessment, and approval process for medical devices before they are supplied in New Zealand. The Government intends to require this for medium- to high-risk devices (such as implantable medical devices) through the new Medical Products Bill.

10 The Medicines Act is outdated and does not meet the needs of patients, practitioners or industry. An amendment to the Act to accommodate the provisions in recommendation 1 would require a substantial amount of work diverting resources from the development of the Medical Products Bill.

11 In September 2024, the Government agreed to replace the Medicines Act with modern regulation of medicines and medical devices under a Medical Products Bill. The purpose of this Bill will be to:

11.1 support improved health outcomes for all New Zealanders by enabling timely access to safe, high quality and effective medical products, and to do this by

11.2 providing cost-effective assurance that medical products meet acceptable standards of safety, quality, and efficacy or performance.

12 The Government believes the Medical Products Bill will be the most appropriate and efficient vehicle to introduce risk-proportionate regulation of medical devices, including contraceptives that are medical devices, which ensures they meet safety, quality and performance standards.

13 The Government notes that delivering a regulatory approval system for medical devices will require primary and secondary legislation, as well as systems and resources to be in place to give effect to the legislation. The Government also notes that the risk-proportionate regulation of medical devices need not always require a local assessment of all devices before they are supplied in New Zealand. Instead, legislation can enable reliance on decisions and assessments undertaken by trusted overseas regulators where appropriate. The lowest-risk products (which do not include implanted devices, such as Essure) can be 'notified' instead of approved. This is aligned with international approaches.

14 Nonetheless, the petition highlights the importance of appropriate regulation for medical devices. The issues raised by the petitioner and Committee, including post-market surveillance for, and reporting harm or injuries from, medical devices will be considered in the development of the Medical Products Bill.

15 **Recommendation 2**: create a legislative mandate for reporting harm or injury caused by medical devices.

16 **Response:** The Government will consider this as part of developing the Medical Products Bill but does not agree to implement this recommendation as a universal obligation or via an amendment to the Medicines Act.

17 As outlined above, the Government is developing a modern Medical Products Bill to replace the Medicines Act. The Medical Products Bill provides the most appropriate vehicle to implement risk-proportionate adverse event reporting requirements, which will require consultation with practitioners, industry, and government agencies such as ACC and the public, including women's health representatives.

18 The Government notes that there are existing systems for collecting information on harms or injuries caused by medical devices, including:

18.1 sharing of information collected by ACC with Medsafe, if ACC believes there is a risk of harm to the public,

18.2 a power under the Medicines Act for the Director-General of Health to request information from the supplier of a medical device if the Director-General believes the device may be unsafe, and

18.3 the Health Quality & Safety Commission national adverse events reporting policy.

19 Moreover, harms arising from medical devices can be due to inappropriate use of a product, as opposed to a defect with the product itself. Health practitioner bodies, including Responsible Authorities established under the Health Practitioners Competence Assurance Act 2003, play a role in overseeing the safe use of medical devices and acting in response to complaints of harm or injury arising from practitioner conduct and clinical practice. The Health and Disability Commissioner also handles complaints about health provider conduct and breaches of the Code of Health and Disability Services Consumers' Rights.

20 As such, implementing this recommendation is complex and involves multiple stakeholders and agencies. It will be important that existing and any new reporting systems enabled under the Medical Products Bill are connected so appropriate actions can be taken.

21 In addition to strengthening reporting requirements, the Medical Products Bill will provide appropriate post-market tools to respond to evidence of harm, or to prevent harm from occurring. For instance, the Bill will enable a range of

regulatory orders, including recall orders and product moratorium orders, which can restrict how and by whom a product is used while further information on its safety is assessed. The Bill will also enable the withdrawal of medical devices from the New Zealand market, when justified.

Conclusion

22 In summary, the Government considers that the recommendations of the Committee will be appropriately addressed in the Medical Products Bill.